

Remarks

Claims 46-72 were pending in the subject application. By this Amendment, claims 46-72 have been cancelled and new claims 73-94 have been added. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Accordingly, claims 73-94 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

The Office Action indicates that the elected subject matter has been accorded the filing date of international application PCT/GB03/04786, *i.e.*, November 7, 2003, for the purpose of examination. Applicants respectfully submit that SEQ ID NO:68 finds clear basis in the priority document, for example, see page 6, lines 6, 13, and 27. Accordingly, Applicants respectfully request the Examiner to reconsider the priority date accorded the claimed subject invention.

The Office Action indicates that the specification should be reviewed for use of trademarks, embedded hyperlinks and/or other form of browser-executable code. Applicants have reviewed the specification and amended the subject specification accordingly. Applicants respectfully submit that no new matter has been added by this amendment and reconsideration and withdrawal of the objection is respectfully requested.

Claim 46(a, i-j) has been rejected under 35 USC §112, second paragraph, as indefinite. Applicants respectfully assert that the claims as filed are definite. However, by this Amendment, Applicants have cancelled claim 46. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested as this issue is now moot.

Claims 46 (a, i-j), 71, and 72 have been rejected under 35 USC §112, first paragraph, as lacking sufficient written description. The Office Action argues:

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the genus of:

a) **fragments** of an alpha-2-macroglobulin-like proteinase inhibitor wherein the fragments comprises or consists, has greater than 80% sequence identity with, has

an antigenic determinant in common with or consists of at least 7 amino acid residues from the amino acid sequence recited in SEQ ID NO: 68, 70 or 72;

b) **functional equivalents** of an alpha-2-macroglobulin-like proteinase inhibitor wherein the functional equivalent is homologous of has greater than 80% sequence identity with, exhibits significant structural homology with a polypeptide comprising the amino acid sequence recited in SEQ ID NO: 68, 70 or 72.

### **Fragments**

The claims recite a genus of **fragments** of an alpha-2-macroglobulin-like proteinase inhibitor wherein the fragments comprises or consists, has greater than 80% sequence identity with, has an antigenic determinant in common with or consists of at least 7 amino acid residues from the amino acid sequence recited in SEQ ID NO: 68, 70 or 72, but do not require that the fragments share any alpha-2-macroglobulin-like proteinase inhibitor activity, a feature deemed essential to the instant invention. In the absence of sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, the claimed invention is not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

### **Functional equivalent**

The claim recites a genus **functional equivalents** of an alpha-2-macroglobulin-like proteinase inhibitor wherein the functional equivalent is a homologous of, has greater, than 80% sequence identity with, exhibits significant structural homology with a polypeptide comprising the amino acid sequence recited in SEQ ID NO: 68, 70 or 72, but the specification failed to support all the possible functional equivalents. The fact that two polypeptides that are homologous in structure or share certain degrees of identity in sequence does not in and of itself required that the two sequences share any functional activity such as alpha-2-macroglobulin-like proteinase inhibitor activity. In the absence of sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, the claimed invention is not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants respectfully traverse the rejection of record.

The claims have been rewritten in this matter in order to address the rejections set forth in the Office Action and now include a recitation of functional activity. For example, the claims now recite polypeptides that have alpha-2-macroglobulin-like proteinase inhibitor activity and have at least 85% sequence identity to SEQ ID NO: 68 or polypeptide that have at least 95% sequence identity to SEQ

ID NO: 70 or 72 and alpha-2-macroglobulin-like proteinase inhibitor activity. As the Patent Office is aware, the written description requirement can be met by disclosure of sufficiently detailed, relevant identifying characteristics, such as sequence information coupled with functional activity (see *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002)). Accordingly, it is respectfully submitted that the claimed invention complies with the written description requirement and reconsideration and withdrawal of the rejection is respectfully requested.

Claim 46(j) has been rejected under 35 USC §112, first paragraph, as non-enabled by the subject specification. The Office Action has rejected the claims on the basis that the specification has not provided sufficient teaching on the immunogenic capacity of the claimed polypeptide or its efficacy as a vaccine. Without agreeing with the Examiner's position, and solely for the purposes of expediting prosecution in this matter to completion, this aspect of the claim has not been incorporated into the newly presented claims and renders this issue moot. Accordingly, reconsideration and withdrawal of the rejection of record is respectfully requested.

Claims 46 (a, i-j) and 71 have been rejected under 35 USC §102(a) as being anticipated by Kekuda *et al.* (U.S. Published Application No. 2004/0002120) and as evidenced by the sequence alignment provided with the Office Action and the instant specification. Applicants respectfully submit that the cited reference fails to anticipate the claimed polypeptide. For example, the cited reference fails to teach a polypeptide that has at least 85% sequence identity to SEQ ID NO: 68 over its full length. Accordingly, reconsideration and withdrawal of the rejection of record is respectfully requested.

Claims 46 (a, i-j), 71 and 72 have been rejected under 35 USC §102(a)/(e) as being anticipated by Rosen *et al.* (U.S. Published Application No. 2003/0044890) and as evidenced by the sequence alignment provided with the Office Action. Applicants respectfully submit that the cited reference fails to anticipate the claimed polypeptide. For example, the cited reference fails to teach a polypeptide that is at least 95% identical to SEQ ID NO: 70 or 72 over its full length. Accordingly, reconsideration and withdrawal of the rejection of record is respectfully requested.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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